DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 7, 2015

Jiangsu Yile Medical Article Co., Ltd
C/O Mr. Charles Mack
Principal Engineer
International Regulatory Consulting
12226 Washington Lane
Parker, AZ 85344

Re: K143070
Trade/Device Name: Disposable Safety Self-destructive Syringes, 5ML
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: MEG, FMI
Dated: May 27, 2015
Received: June 04, 2015

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143070

Device Name
Disposable Safety Self-destructive Syringes, 5ML

Indications for Use *(Describe)*

The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. In addition, it is designed to aid in the prevention of needle stick injuries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K143070

510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements with requirements of CFR Part 807.92.

Date: June 24, 2015

1. Company and Correspondent making the submission:

Name – Jiangsu Yile Medical Article Co., Ltd
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Contact - Mr. Feng Xingyuan
General Manager
Email - charliemack@irc-us.com

Primary contact and correspondent:
Name: Charles Mack
Address: 12226 Washington Lane, Parker, Arizona 85344
Phone" 931-625-4938
Email: charliemack@irc-us.com

2. Device :

Trade/proprietary name: Disposable Safety Self-destructive Syringes, 5ML
Common Name : Syringe, Antistick; needle; hypodermic, single lumen
Classification Name : Piston syringe, Hypodermic single lumen needle

3. Predicate Devices :

lnviroSnap Safety Syringe 1ML, 3ML, 5ML, 10ML, 20ML, (K092430)

4. Classifications Names & Citations :

21CFR 880.5860, MEG, syringe, antistick; 21CFR880.5570, FMl, needle, hypodermic, single lumen; both classifications are Class 2

5. Description :

The JlANGSU YlLE MEDlCAL ARTlCAL C0., LTD Disposable Safety Self-destructive Syringes, 5MLs are single lumen hypodermic needles with a safety mechanism to prevent needle stick after the usage. The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. ln addition, it is designed to aid in the prevention of needle stick injuries.

The syringes are made of a protector, needle, up connector, 0-ring seal, down connector, barrel, piston and plunger. The syringe and body are constructed of Polypropylene (PP). The piston and 0-ring seal are made of natural rubber. Lumens are constructed of 304 Stainless Steel.

6. lndication for use :

The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. ln addition, it is designed to aid in the prevention of needle stick injuries.

7. Technological Characteristics and Comparison with predicate device :

Jiangsu Yile Medical Article Co., Ltd believes that the Disposable Safety Self-destructive Syringes, 5ML are substantially equivalent to the lnviroSnap Safety Syringe 1ML, 3ML, 5ML, 10ML, 20ML (K092430).

Please note the comparison table on the following page, which demonstrates the similarities of the Jiangsu Yile Medical Article Co., Ltd Disposable Safety Self-destructive Syringes, 5MLs and the predicate device.

Element of comparison	Subject Device	Claimed SE Device
Company	JIANGSU YILE MEDICAL ARTICLE CO.,LTD	INVIRO MEDICAL DEVICES, INC.
FDA510(K) Number	K143070	K092430
Device Name	Disposable Safety Self-destructive Syringes, 5ML	InviroSnap Safety Syringe
Model Number	5ML	1, 3, 5, 10 and 20ML
Intended Use	The Disposable Safety Self-destructive Syringe is used to inject fluids into, or withdraw fluids from the body. In addition, it is designed to aid in the prevention of needle stick injuries.	The InviroSnap Safety Syringe is used to inject fluids into, or withdraw fluids from, the body. In addition, the InviroSnap Safety Syringe is designed to aid in the prevention of needle stick injuries.
Principle of operation	Identical	After use, the health care professional fully depresses the plunger to engage the luer assembly. Once the luer assembly is engaged, pulling back the plunger causes the Adapter and the attached needle to be withdrawn into the safety of the barrel. In this position against the flange, lateral pressure on the plunger results in a controlled fracture of the plunger. Both the syringe and plunger are discarded in a sharps container.
Safety feature	Identical	Manually retractable safety syringe with permanent disable
Material		
Barrel	PP	PP
Plunger	PP	PP
Piston	Natural Rubber	Natural Rubber
Needle	Stainless Steel	Stainless Steel
Needle Protector	PP	PP
Lubricant	Polydimethylsiloxane Oil	Silicone Oil
Specific drug use	Identical	Conventional drugs
Sterilization	Identical	EO Sterilization
Needle length	1 1/2 Inch	1 1/4 Inch
Needle gauge	21G	21/22/23G
Needle tip configuration	Identical	Tri-Beveled Tip
Wall type	Identical	Regular wall
Nozzle type	Identical	Needle and hub are separated to the syringe
Barrel marking specs	Identical	Conforms to ISO 7886-1
Gradations legibility	Identical	0.2ml
Needle cover color	Identical	Clarity
Lubricant composition	Polydimethylsiloxane Oil	Silicone Oil
Lubricant amount/cm^2	Identical	<0.25mg/cm^2
Barrel transparency	Identical	Transparency
Delivery accuracy	Identical	Conforms to ISO 7886-1
Biocompatibility	Identical	Conform to ISO 10993-1
Syringe type	Identical	Antistick syringe
Reuse	Identical	Single use only
Sterility	Identical	Sterile

8. Non-clinical and Performance Tests :

List the actual tests performed on the subject device

Biocompatibility:
Cytotoxicity Test (ISO10993-5: 2009)
Sensitization Test (ISO10993-10: 2010)
Intracutaneous Reactivity Test (ISO10993-10: 2010)
Acute Systemic Toxicity Test (ISO 10993-11: 2006)
Hemolysis Test (ASTM F756-13)

Performance:
ISO 7886-1:1993/ Corrigendum 1:1995 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 7864:1993 Sterile hypodermic needles for single use
ISO 9626: 2001 Stainless steel needle tubing for the manufacture of medical devices
ISO 23908: 2011 Sharps injury protection-requirements and test methods-sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
ISO 7886-4:2006 Sterile hypodermic syringes for single use-Part 4: Syringes with re-use
ISO 594/1, Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 1: general requirements.
ISO 594-2 Second edition 1998-09-01, Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 2: lock fittings.
USP 788 Light Obscuration Particle Count Test

Simulated clinical use:
FDA guidance “Guidance for industry and FDA Stuff, Medical Devices with Sharps Injury Prevention Features, August 9, 2005”.

Package and Shelf Life:
- Real Time Stability Test
- Accelerated Aging Test
- Sterile test
- Vacuum leak test
- Dye penetration test
- Agar contact-attack test (Microbial barrier properties)
- Tensile Seal Strength Test

Related standards:

ISO11607-1: Packaging for terminally sterilized medical devices - Part1: Requirements for materials, sterile barrier systems and packaging systems.

ISO11737-2: Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process.

ASTM F1980-07: Standard guide for accelerated aging of sterile barrier systems for medical devices.

ASTM D3078-02: Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission.

ASTM F1929-98: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

ASTM F88 -09 Standard Test Method for Seal Strength of Flexible Barrier Materials

ISO7886-1: Sterile hypodermic syringes for single use - Part1: Syringes for manual use.

ISO 23908: Sharps injury protection-requirements and test methods-sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

ISO7864: Sterile hypodermic needles for single use.

All test results were satisfactory.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Jiangsu Yile Medical Article Co., Ltd concludes that the Disposable Safety Self-destructive Syringes, 5ML are substantially equivalent to predicate devices as described herein.

END